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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,668	09/13/2001	Jack Thacher Leonard	MCA-448 PC/US	8911

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MILLIPORE CORPORATION
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EXAMINER

KIM, SUN U

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,668

Applicant(s)

LEONARD, JACK THACHER

Examiner

John Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 6) ☐ Other: _____

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1. If applicant desires priority under 35 U.S.C. 111(a) based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. ____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the

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required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claims 1-2 are indefinite for failing to particularly point out to what a volume of liquid is being added. Examiner suggests an insertion of a liquid holding structure e.g. reservoir above the membrane in claims 1-2. Recitations of "the device" in claims 7-9, 11 and 12-13 and "the plate" in claims 10 and 14 lack positive antecedent basis. Claims 10 and 14 are indefinite for failing to particularly point out the relationship between the ultrafiltration and the wells in the plate. Recitation of "about 500 Kdaltons" in dependent claim 15 broadens the scope of the limited range of 300KD in the independent claim 1. Recitation of "about 3

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(daltons)" in dependent claim 16 broadens the scope of the limited range of 100 D in the independent claim 2.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 7, 15, 17 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,604,754 (hereinafter referred to as Koyama et al). Koyama et al teach a process for concentration of proteins comprising the steps of providing ultrafiltration membrane having a molecular cutoff between 1 kD and 100 kD and made of cellulose series materials in a well, adding a volume of less than 100 microliters of bovine serum sample, subjecting the sample on the membrane to a positive pressure i.e. injector syringe or centrifugation till proteins are concentrated on the membrane (see figures 1-5; col. 1, lines 7-12, 44-49; col. 3, line 12 – col. 4, line 18).

7. Claims 1, 7-8, 10, 15 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 92/13963 (hereinafter referred to as WO '963). WO '963 teaches a process for concentration of nucleic acids comprising the steps of providing ultrafiltration membrane having a molecular cutoff of 25 kD in a single or multiple wells in a plate (see 42 wells in figure 2), adding a volume of less than 100 microliters of digested DNA mixture sample, subjecting the sample on the membrane to a vacuum pressure till RNA are isolated on the membrane (see figures 1-2, 4; page 8, lines 4-24; page 13, lines 1-5; page 14, lines 23-30; page 15, line 15 – page 16, line 25).

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8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koyama et al.

Koyama et al teach the process for concentrating proteins as described in above paragraph 6.

Claim 5 essentially differs from the method of Koyama et al in reciting a positive pressure differential from about 5 to about 80 psi. Koyama et al teach that filtration of samples are effectively performed under a centrifugal force or under pressure applied as a driving force of filtration (see col. 3, lines 50-53). It would have been obvious to a person of ordinary skill in the art to apply a necessary positive pressure including claimed pressure to obtain desired concentration of proteins by filtering out low molecular weight through the membrane.

10. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO '963. WO '963 teaches the process for concentration of nucleic acids as described in above paragraph 7.

Claim 3 essentially differs from the method of WO '963 in reciting a vacuum pressure differential from about 169 millibars to about 914 millibars. WO '963 teaches that filtration of samples are performed under vacuum to draw low molecular weight below the cutoff of the membrane out of the sample solution (see page 15, line 31 – page 16, line 2). It would have been obvious to a person of ordinary skill in the art to apply a necessary vacuum pressure including claimed pressures to obtain desired concentration of nucleic acids by filtering out low molecular weight through the membrane.

11. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO '963 as applied to claim 1 above, and further in view of U.S. Patent No. 4,902,481 (hereinafter referred to as Clark et al '481). WO '963 teaches a process for concentration of nucleic acids described in above paragraph 7. Claim 10 essentially differs from the method of WO '963 in reciting a 96 well plate. Clark et al '481 teach that 96-well filtration plate is typically used (see col. 1, lines 21-23). It would have been obvious to a person of ordinary skill in the art to use a well-known 96-well filtration plate in the method of WO '963 for concentrating nucleic acids.

12. Claims 2, 4, 6, 11-14, 16, 18 and 22 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 4,632,761 and 4,832,851 and 5,141,718 and 5,223,133 and 5,679,310 and 5,047,215 and 6,463,647 and 4,522,713 and 6,359,114 teach microfiltration or ultrafiltration apparatuses and/or methods.


14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response after final action is (703) 872-9311, and the fax phone number for all other official faxes is (703) 872-9310.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.


John Kim
Primary Examiner
Art Unit 1723

J. Kim
June 12, 2003